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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,636	03/29/2004	Nehal Mohamed	ELI-029	3487

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,636	MOHAMED ET AL.	
	Examiner	Art Unit	
	Khatol S. Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007 and 05 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 63-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 , 63-74 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/29/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/05/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to restriction of 02/09/2007 is acknowledged. Applicants' amendments of 3/22/2007 is acknowledged. Claim 1 has been amended. Claims 2-62 have been canceled. New claims 63-76 have been added.

Status of Claims

2. Claims 1 and 63-76 are pending.

Note: Applicants in their remarks on pages 4 and 5 recite claims 63-77 as being added. This must have been a typographic error, since applicants only added new claims 63-76. Clarification is requested.

Information Disclosure Statement

3. The information disclosure statement filed 04/05/2007 has been considered. Initialed copy is enclosed.

Election/Restrictions

4. Applicants' election with out traverse of 02/09/2007 is acknowledged. Applicants elected group I, which is drawn to a bispecific molecule Applicants have submitted new claims 63-76, which directed to bispsecific molecules and applicants requested that these claims should be included in group I. For election of species applicants elected an E 11 antibody from claim 76.

Claims 1 and 63-76 are under consideration.

Drawings

5. The drawing submitted on 3/29/2004. has been accepted by the office.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the

applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 65, 66, 67, 68, 71, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. US Patent 5,470,570.

Claim 1 is drawn to a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen or toxin.

Taylor et al. teach a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen or toxin (see claims specifically claim 1, column 5 lines 24-30 and column 7 lines 5-15).

Taylor et al. teach that the anti-CR1 antibody is cross-linked to the non-neutralizing antibody, and cross-linking agents (see column 3, lines 7-15). Taylor et al. teach monoclonal antibodies (see column 1, line 64 summary of invention). Taylor et al. also teach reduced immunogenicity of one or more antibodies (see column 7, lines 31-40).

Taylor et al. teach multiple full-length antibodies (see table 1). The prior art anticipates the claimed invention.

8. Claims 1, 65, 66, 67, 68, 71, 72 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindorfer et al. (Journal of Immunology Vol. 167, PP. 2240-2249, 2001).

Claim 1 is drawn to a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen or toxin.

Lindorfer et al. teach a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen or toxin (see abstract and page 2241).

Lindorfer et al. teach that the anti-CR1 antibody is cross-linked to the non-neutralizing antibody, and cross-linking agents (see abstract and page 2241). Lindorfer et al. teach

monoclonal antibodies (page 2241 material and methods). Lindorfer et al. teach anti-CR1 7G9 monoclonal antibodies (see page 2241). Lindorfer et al.. also teach reduced immunogenicity of one or more antibodies (see column 7, lines 31-40). Lindorfer et al. teach multiple full-length antibodies (see page 2241). The prior art anticipates the claimed invention.

9. Claims 1, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73 and 74 rejected under 35 U.S.C. 102(e) as being anticipated by Mohamed et al. 2006/0140931 A1 filed September 16, 2003 claiming priority to a provisional application file on September 16, 2002.

The applied reference have common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 1 is drawn to a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen or toxin.

Mohamed et al. teach a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen or toxin (see abstract, claims and page 4, paragraph 0033). Mohamed et al. teach that the anti-CR1 antibody is cross-linked to the non-neutralizing antibody, and cross-linking agents such as PEG (see page 5, paragraph 0037 and claim 5). Mohamed et al. teach monoclonal antibodies (page 4 and 5, paragraphs 0033 and 0037). Mohamed et al. teach anti-CR1 7G9 monoclonal antibodies (see page 4, paragraph 0033 and claims 11, 61). Mohamed et al. also teach reduced immunogenicity of one or more antibodies (see column 7, lines 31-40). Mohamed et al. teach multiple full-length antibodies and fragments including Fab, Fab', (Fab') 2, Fv, scFv, or scab (see pages 4, 6, 8, paragraphs 0035, 0040, 0064 and claim 3). Mohamed et al. teach a bispecific molecule, wherein the anti-CR1 antibody is cross-linked to the non-neutralizing antibody (see abstract, and claims 14, 64). The prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 63, 65, 66, 67, 68, 71, 72, 74 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindorfer et al. (Journal of Immunology Vol. 167, PP. 2240-2249, 2001) in view of Anderson et al. (US 6,194,549 B1).

Lindorfer et al. teach a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen or toxin (see abstract and page 2241).

Lindorfer et al. teach that the anti-CR1 antibody is cross-linked to the non-neutralizing antibody, and cross-linking agents (see abstract and page 2241). Lindorfer et al. teach monoclonal antibodies (page 2241 material and methods). Lindorfer et al. teach anti-CR1 7G9 monoclonal antibodies (see page 2241). Lindorfer et al.. also teach reduced immunogenicity of one or more antibodies (see column 7, lines 31-40). Lindorfer et al. teach multiple full-length antibodies (see page2241). Lindorfer et al. teach that studies in monkey models indicate that HP (heteropolymers or bispecific monoclonal antibodies) can be used to bind prototype pathogens see 2240 right column. Lindorfer et al. do not teach an antibody that recognize *Staphylococcus* aureus protein A.

Anderson et al. teach monoclonal antibodies, fragments and derivatives that can be used in protein an immunoassay (see column 19, lines 45-55 and column 16, lines 10 to 55). Anderson et al. teach antibodies that bind Staphylococcus aureus Cowan strain I (see column 18, lines 19-40). Anderson et al. also teach 3D2 monoclonal antibody (see column 19).

It would have been *prima facie obvious* to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindorfer et al., a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to a bacterial antigen (i.e. Pseudomonas) with the teachings of Anderson et al, et al. monoclonal antibodies that binds *Staphylococcus* aureus protein A to obtain a bispecific molecule comprising an anti-CR1 antibody linked to a non-neutralizing antibody that binds to *Staphylococcus* aureus protein A. One of skilled in the art would have been motivated by the teaching of Lindorfer et al. that studies in monkey models indicate that HP (heteropolymers or bispecific monoclonal antibodies) used to bind prototype pathogens for targeting them and removing them for circulation see 2240 right column. One of skilled in the art would have also been motivated to apply Anderson et al. monoclonal antibodies of that bind *Staphylococcus aureus* protein A for therapeutic purposes. (see Anderson et al, column 3, lines 5-20).

Status of the Claims

12. Claims 1, 63-74 and 76 are rejected.

Claim 65 is objected to as being depending from rejected claim 1.

Claim 65 is free of prior art.

Conclusion

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Khatol Shahnan-Shah . B.S.,
Pharm, M.S.
Biotechnology Patent Examiner
Art Unit 1645
June 10, 2005

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER